IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		**Docket No.:**	**4179-128**
Applicants:	**SHAH, Tilak M.**	**Conf. No.:**	**8353**
Application No.:	**10/815,282**	**Art Unit:**	**1711**
Date Filed:	**April 1, 2004**	**Examiner:**	**Thao T. Tran**
Title:	**EXTRUSION LAMINATE POLYMERIC FILM ARTICLE AND GASTRIC OCCLUSIVE DEVICE COMPRISING SAME**	**Customer No.:**	**23448**

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/vincent k. gustafson/

REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41 ON APPEAL IN U.S. PATENT APPLICATION NO. 10/815,282

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This responds to the Answer Brief mailed on June 12, 2008 in the above-identified patent application.

Pursuant to 37 CFR 41.41(a)(1), the time for responding to the Answer Brief was set at two months from the mailing date of the Examiner's Answer Brief, or by August 12, 2008

A. The Examiner Misapprehends the Disclosure of Connors, Which Fails to Teach Any Multilayer Film Balloon That in an Inflated State is Non-Pillowed and Spheroidal in Shape

In the Answer Brief, the examiner discusses different embodiments disclosed by Connors (U.S. Patent No. 6,976,950), with reference to Connors Figure 5 and Figure 16C. (Answer Brief, page 3.) In discussing the container 68 depicted in Connors Figure 5 (reproduced below together with the associated Figure 5A), the examiner characterizes the "inflatable container 68 [as] having a generally circular profile ... and a spherical configuration."

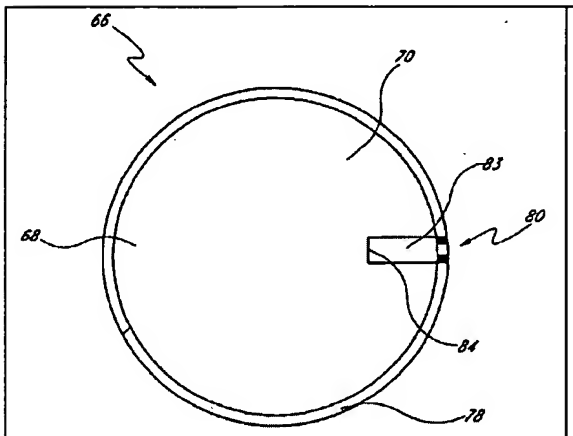


FIG. 5

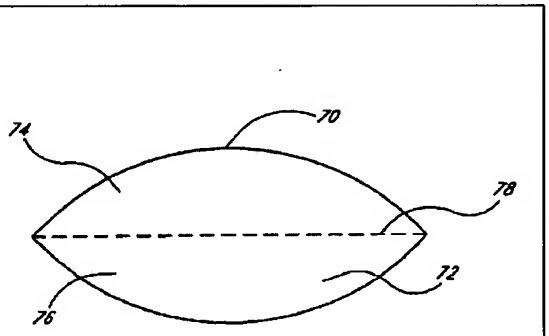


FIG. 5A

All of the pending claims recite, *inter alia*,:

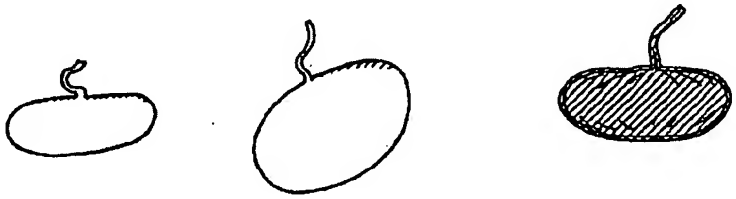
> "a balloon that in an inflated state is **non-pillowed** and **spheroidal** in shape, formed from two vacuum thermoformed half-sections of a **multilayer film** ... wherein ... the vacuum thermoformed half-sections are **bonded** to one another **along peripheral portions** thereof to form a **peripheral seam**."

In discussing the embodiment shown in Connors Figures 5-5A, the examiner fails to address the fact that Connors' inflatable container 68 is clearly **pillowed** in shape (i.e., along seam 78 shown in Figure 5A), and thus does not embody "a balloon that in an inflated state is non-pillowed" as required by Applicant's claims. Although such inflatable container 68 of Connors is circular in

shape when from above (see Connors Figure 5), the container 68 **cannot be fairly characterized as "spherical"** (as stated by the examiner at page 3 of the Answer Brief) when viewed from the *side* as shown in Connors Figure 5A.

While the embodiment of Connors Figure 5 clearly includes a seam 78 (which is consistent with bonding between different sheets), the different embodiment shown in Connors **Figure 16C** (reproduced below) **does <u>not</u> clearly depict any seam** – nor does Connors mention any seam in conjunction with the embodiment of Figure 16C.

FIG. 16C



The foregoing embodiment of Connors Figure 16C fails to embody the subject matter of Applicant's pending claims, which require the presence of "**half-sections** [that] are bonded to one another along peripheral portions to form a **<u>peripheral seam</u>**."

Furthermore, the examiner has erroneously characterized the disclosure of Connors Figure 16C by suggesting that various features described in Connors' text are necessarily included in such embodiment. In particular, the examiner states:

> "[i]n another embodiment (see Fig. 16C), Connors teaches a balloon that is non-pillowed and spheroidal in shape; the wall of the device comprising at least one gas barrier layer and at least one moisture barrier layer."

(Answer Brief, page 3.)

With respect to the presence of a moisture barrier layer in the embodiment of Connors Fig. 16C, the examiner points to col. 23, lines 1-20 of Connors, and with respect to the gas barrier layer, the examiner points to col. 23, lines 44-54 of Connors. The problem with such allegation is that **<u>the foregoing excerpts of Connors do NOT clearly relate to Figure 16C</u>**. .

The following excerpts of Connors represent the only portions of such patent that DO clearly relate to Figure 16 – but none teach or suggest that any embodiment of Figure 16 embodies multiple layers that are peripherally bonded to one another to form a peripheral seam.

> **Referring to FIG. 16, there is illustrated a variety of shapes for the attenuation device, 66** of the inflatable container variety. The devices used in embodiments of the present invention may take many shapes. In some instances **it may be desirable for manufacturing purposes to have the shape resemble dip-molded devices** like condoms, surgical glove fingers, or children's toys.

(Connors, col. 22, lines 26-32.)

> FIG. 16A illustrates a toroidal embodiment, in which a plurality of central spokes are provided. FIG. 16B illustrates a crescent or "C" shaped attenuation device. **Any of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C**, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section. FIG. 16D illustrates a less arcuate variety as shown in FIG. 16 B. In general, the attenuation device 66 may take any of a variety of forms which provides a sufficient volume to achieve the desired attenuation function, and which will minimize or eliminate risk of loss or obstructing outflow through the urethra.

(Connors, col. 24, lines 14-26.)

> In other embodiments of the present invention, the attenuation device may resemble a small three-spoked automotive steering wheel, or a rotating toroidal space station. See FIG. 16 A. The outer ring would contain the attenuation device; the inwardly radiating spokes would provide fluid conduits and mechanical support for the secondary device attachment.

(Connors, col. 28, lines 37-48.)

The portion of Connors at column 22, line 40 through column 24, line 13 discusses various different balloon construction methods and various different materials – **but without any specific reference to Figure 16, or to the embodiment of Figure 16C in particular**. Instead, a review of Connors at column 22, line 40 to column 24, line 13 indicates that the patentee has simply provided general guidance for constructing various different types of balloon devices.

Among the various balloon materials and construction methods disclosed at column 22, line 40 to column 24, line 13 of Connors, it is further noted that certain materials and methods are compatible with one another and suitable for making particular balloon shapes, whereas other materials and methods are not. For example, **dip molding** and **extrusion** are mentioned at col. 22, lines 41-43 – immediately following a discussion of Figure 16 generally. Such balloon fabrication techniques typically do not involve use of multi-layer sheets. This principle is consistent with the testimony of Mr. Shah that "[o]ne skilled in the art would understand ... that not every balloon fabrication method mentioned by Connors is compatible with every particular balloon shape that is mentioned by Connors." Shah Declaration, ¶ 7.

In short, Figures 5-5A of Connors relate to a balloon 68 fabricated with two circular sheets 74, 76 of material that are peripherally bonded to form a seam 78, but such balloon 68 is clearly **pillowed** in shape – representing a clear teaching away from the subject matter of Applicant's claims. Even though Figure 16C of Connors depicts a balloon that is oval in shape and non-pillowed, such embodiment **lacks any discernable peripheral seam** and, contrary to the examiner's representation, nothing in Connors teaches or clearly suggests that such embodiment of Figure 16C should be fabricated from peripherally bonded multi-layer sheets.

B. Applicant's Arguments Distinguishing Connors are NOT Based Solely on Balloon Shape

The examiner contends that the "main focus of Applicant's arguments throughout the Appeal Brief is on the shape of the balloon." (Answer Brief, page 4.) Such representation is incomplete, as Applicant does not purport to have invented merely a "spheroidal and non-pillowed balloon." It is well-known and trivially simple to fabricate a single-layer elastomeric balloon (e.g., via dip molding) bearing such shape. A key inventive aspect of the pending claims, however, is "a balloon that in an inflated state is **non-pillowed** and **spheroidal** in shape, formed from two vacuum thermoformed half-sections of a **multilayer film** ... wherein ... the vacuum thermoformed half-sections are **bonded** to one another **along peripheral portions** thereof to form a **peripheral seam.**" **It is NOT simple to achieve a non-pillowed, spheroidal balloon from two peripherally bonded multilayer films**. The only way known by Applicant to achieve

such result is to shape the multilayer films by vacuum thermoforming – and such technique was NOT known in the art at the time the present application was filed.[1]

CONCLUSION

For the reasons stated herein, along with the reasons stated in Applicant's Appeal Brief filed on March 20, 2008, the rejections of claims 74-108 under 35 U.S.C. § 103 should be reversed.

Respectfully submitted,

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[1] As evidenced by the issuance to the same Applicant herein of U.S. Patent No. 6,712,832, Applicant has pioneered methods for manufacturing low-pressure balloons from thin polymeric materials, including the steps of heating the thermoplastic polymer-based thin films in a vacuum thermoforming die (e.g., a die having a non-planar surface and passages to allow application of suction a film during heating thereof) to sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof. The content of U.S. Patent No. 6,712,832 was not publicly available until after the filing of the present patent application.